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EXAMINER

OLSEN, KAJ K

ART UNIT PAPER NUMBER

1753

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/630,441

Applicant(s)

HODGES ET AL.

Examiner

Kaj K Olsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9-23-04;7-29-03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Claim Objections*

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). There are two claim 13s, three claim 14s and no claim 15.

The second claim 13 is now renumbered as claim 14. The three claim 14s have been renumbered as 15-17 respectively. Claims 16 and 17 have been renumbered as claims 18 and 19 respectively. The dependency of newly number claims 15-17 has been interpreted as depending from claim 14 and not claim 13.

### *Double Patenting*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 6, 7, 10, 11, 13, 18 and 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4 and 11 of U.S. Patent

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No. 6,652,734. Although the conflicting claims are not identical, they are not patentably distinct from each other. With respect to claim 1 of the instant invention, it differs from claim 1 of the patent in only generally identifying the sulfur containing moiety in contrast to the specific 3-carboxythiophene of claim 1 of the patent. However, claim 1 of the patent is fully encompassed by claim 1 of the instant invention because "sulfur containing moiety" would read on 3-carboxythiophene. Similarly, the carboxyl group of 3-carboxythiophene would be fully encompassed by the hydrophilic groups of claims 6 and 7 of the instant invention and the thiophene group would be fully encompassed by the specified aromatic spacer group of claims 10 and 11 of the instant invention. Claim 13 of the instant invention specifically identifies the compound 3-carboxythiophene. Claim 18 of the instant invention differs from claim 4 of the patent by similarly not specifying the specific composition of the sulfur containing moiety. Hence claim 4 is fully encompassed by claim 18 of the instant invention. Although claim 16 specifies greater temporal stability (unlike claim 4), it is clear from claim 1 of the patent that the 3-carboxythiophene of the patent meets this limitation. Claim 19 of the instant invention differs from claim 11 of the patent for the same reasons highlighted above for claims 1 and 18.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 13-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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5. Claim 13 appears to misspell 3-mercaptopropanoic acid.
6. Claim 14 depends from claim 12, but the examiner believes it should depend from claim 13. First, claim 14 specifies "the compound", which would lack antecedent basis as it depends from claim 12 (claim 13 has "a compound" that would provide appropriate antecedent support). Second, claim 14 specifies the compound be stereospecific. Applicant never disclosed a material having methylene or ethylene groups (as claim 12 requires) that is also stereospecific. Applicant's only specific stereospecific molecules in the originally filed disclosure were the cysteines and cystine, none of which have methylene or ethylene groups and which are in claim 13. Hence the examiner will construe claim 14 as depending from claim 13, but clarification and correction are required.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-7, 10-13, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al (J. Electroanal. Chem., 178 (1984), pp. 69-86) in view of Maley et al (USP 5,529,676).

10. With respect to claim 1, Allen discloses a coated metal electrode comprising numerous different sulfur-containing moieties for said coating. See p. 72 for a discussion of the metal electrode and table 1 for a listing of the moieties being relied on. Allen does not explicitly disclose overcoating this coating with a surfactant. Maley teaches in an alternate coated electrode that subsequent treatment of the electrode with a surfactant improves the storage life and the wetting properties of the electrode. See col. 30, line 56 through col. 31, line 8 and fig. 22 and 23. Said subsequent treatment of the electrode with surfactant would read on the specified "overcoating" giving the claim language its broadest reasonable interpretation. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Maley for the electrode of Allen in order to improve the storage life and wetting properties of the electrode.

11. With respect to claims 2-4, see structures 2, 19 and 46 from fig. 3.

12. With respect to claim 5, see elements 28-30 of Table 1.

13. With respect to claims 6 and 7, see structures 4, 10a, 14a-16a from fig. 3.

14. With respect to claims 10 and 11, see structure 4 from fig. 3.

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15. With respect to claim 12, this only further limits claim 11 when alkyl groups are chosen from claim 11. Because Allen teaches the use of aromatic groups (see above), Allen reads on claim 12 when aromatic groups are chosen from claim 11.

16. With respect to claim 13, see elements 7 and 28 from table 1.

17. With respect to claim 18, Allen teaches contacting a metal electrode with a sulfur containing moiety (p. 72), but doesn't teach contacting the electrode with a surfactant. As discussed above, Maley teaches in an alternate coated electrode that subsequent treatment of the electrode with a surfactant improves the storage life and wetting properties of the electrode. See col. 30, line 56 through col. 31, line 8 and fig. 22 and 23. Said subsequent treatment of the electrode with surfactant would read on the specified "overcoating" giving the claim language its broadest reasonable interpretation. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Maley for the electrode of Allen in order to improve the storage life and wetting properties of the electrode.

18. With respect to claim 19 (those limitations not covered above), Allen utilizes the electrode as a measurement means for determining the presence of cytochrome c in the solution (see abstract, pp. 72-75 and fig. 1). This would read on the claimed "obtain a measurement indicative of a presence of an analyte in the sample".

19. Claims 1, 2 and 6-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlereth et al (Electroanalysis 1995, 7 (1), pp. 46-54) in view of Maley et al (USP 5,529,676).

20. With respect to claim 1, Schlerich discloses a coated metal electrode where the metal electrode comprising a coating of a sulfur containing moiety comprising cysteine. See Abstract and Scheme 1. Schlerich does not explicitly disclose the use of an overcoating of surfactant.

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Maley teaches in an alternate coated electrode that subsequent treatment of the electrode with a surfactant improves the storage life and wetting properties of the electrode. See col. 30, line 56 through col. 31, line 8 and fig. 22 and 23. Said subsequent treatment of the electrode with surfactant would read on the specified “overcoating” giving the claim language its broadest reasonable interpretation. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Maley for the electrode of Schlereth in order to improve the storage life and wetting properties of the electrode.

21. With respect to claim 2, see scheme 1 of Schlereth.
22. With respect to claims 6-9 and 13, see the cysteine of scheme 1.
23. With respect to claims 10 and 11, scheme 1 also shows examples of alkyl and aromatic spacers.
24. With respect to claim 12, this only further limits claim 11 when alkyl groups are chosen from claim 11. Because Schlereth teaches the use of aromatic groups (see above), Allen reads on claim 12 when aromatic groups are chosen from claim 11.
25. With respect to claims 14-17, cysteine is inherently a stereospecific molecule. Although Schlereth does not specify which form of cysteine is present, Schlereth discusses no criticality as to the choice of isomer is present and one possessing ordinary skill in the art would have been motivated to utilize either the D or L isomer (or both) because they would all provide the desired monolayer for the electrode.
26. With respect to claim 18, Schlereth teaches contacting a metal electrode with a sulfur containing moiety (see section 2.1.1), but doesn't teach contacting the electrode with a surfactant. As discussed above, Maley teaches in an alternate coated electrode that subsequent



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treatment of the electrode with a surfactant improves the storage life and wetting properties of the electrode. See col. 30, line 56 through col. 31, line 8 and fig. 22 and 23. Said subsequent treatment of the electrode with surfactant would read on the specified "overcoating" giving the claim language its broadest reasonable interpretation. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Maley for the electrode of Schlereth in order to improve the storage life and wetting properties of the electrode.

27. With respect to claim 19 (those limitations not covered above), Schlereth utilizes the electrode to obtain a measurement of phenothiazine or NADH. See section 1 or 3.1. This would read on the claimed "obtain a measurement indicative of a presence of an analyte in the sample".

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Thursday from 5:30 A.M. to 3:00 P.M. and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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March 3, 2005



**KAJ K. OLSEN**  
**PRIMARY EXAMINER**